DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 6 2000

Re: Teslascan
Docket No.: 98E-0479

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,933,456, filed by Nycomed Salutar, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Teslascan, the human drug product claimed by the patent.

The total length of the regulatory review period for Teslascan is 3,129 days. Of this time, 2,325 days occurred during the testing phase and 804 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 5, 1989.

   The applicant claims May 10, 1989, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 5, 1989, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 15, 1995.

   The applicant claims November 7, 1995, as the date the new drug application (NDA) for Teslascan (NDA 20-652) was initially submitted. However, FDA records indicate that NDA 20-652 was submitted on September 15, 1995.

3. The date the application was approved: November 26, 1997.

FDA has verified the applicant's claim that NDA 20-652 was approved on November 26, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: John Kappos
Lyon & Lyon
47th Floor
633 West Fifth Street
Los Angeles, CA 90071-2066